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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/644,387	08/23/2000	Gregory E. Agoston	05213-0541	1513

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JOHN S. PRATT  
KILPATRICK STOCKTON LLP  
1100 PEACHTREE  
SUITE 2800  
ATLANTA, GA 30309

EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/09/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/644,387

Applicant(s)

AGOSTON ET AL.

Examiner

Barbara P Badio, Ph.D.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 14-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 21-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**First Office Action on the Merits of a RCE**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 7, 2002 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Information Disclosure Statement***

3. The examiner is requesting another copy of the supplemental information disclosure statement filed December 14, 2001 and any other information disclosure statement filed in the present application.

***Claim Rejections - 35 USC § 102***

4. The rejections of claims 1-13 and 21-25 under 35 USC 102(b) over (a) D'Amato et al. ('074); (b) Clark et al. ('168) and (c) Fotsis et al. ('900) are withdrawn.

**5. The rejection of claims 1-13 and 21-25 under 35 USC 102(e) over Stewart et al. ('966) is withdrawn.**

***Claim Rejections - 35 USC § 103***

**6. The rejection of claims 1-13 and 21-25 under 35 USC 103(a) over D'Amato et al. et al. ('074), Clark et al. ('168), Fotsis et al. ('900) or Stewart ('966) is maintained.**

Applicant argues that the skilled artisan does not recognize other steroids as contaminants or impurities in 2-methoxyestradiol compositions and thus, it cannot be assumed that the 2-methoxyestradiol of the cited references is pure. Applicant's argument is not persuasive for the following reasons.

Utilizing a pure form of any pharmaceutical agent in the medical art would be obvious to the skilled artisan because of the desire to reduce any adverse effect caused by contaminants. Obtaining a pure form of a steroid compound free of any contaminant, including other steroids, would be obvious to the skilled artisan because the skilled artisan would recognize that the terms "impurities" and "contaminants" are inclusive and, thus, refer to that which is not desired. The fact that the prior art recognizes the properties of other steroidal compounds does not imply that said compound(s) are not obtainable or desired in pure form. The fact remains that purer form of compounds useful as therapeutic agents are desired in the pharmaceutical art.

In addition, the data sheet from Sigma discloses the claimed compound can be obtained in pure form of a **minimum** of 98% purity as determined by HPLC. Said would

imply that the compound which is 98-100% pure as determined by HPLC was obtainable by the method utilized by Sigma.

Applicant also stated that there are no references cited by the PTO that shows that steroid contaminants are absent. However, the references do not show that said steroid contaminants are present and, thus, based on the level of skill of the artisan in the pharmaceutical art, the ordinary artisan would have the reasonable expectation that the compound is in pure form.

For these reasons and those given in previous Office Actions, the rejection of claims 1-13 and 21-25 under 35 USC 103(a) over D'Amato et al. et al. ('074), Clark et al. ('168), Fotsis et al. ('900) or Stewart ('966) is maintained.

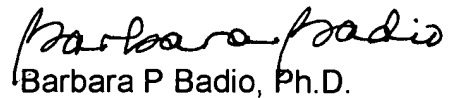
#### ***Telephone Inquiry***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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A handwritten signature in black ink, appearing to read "Barbara P. Badio". The signature is fluid and cursive, with the first name "Barbara" being more prominent.

Barbara P Badio, Ph.D.

Primary Examiner

Art Unit 1616

BB

August 8, 2002